DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18,2014

Jensen Industries, Inc.
Jordan Schreck
Quality Manager
50 Stillman Road
North Haven, CT 06473

Re: K142043
Trade/Device Name: InSync ZR High Translucency Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: II
Product Code: EIH
Dated: October 9, 2014
Received: October 10, 2014

Dear Mr. Schreck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section C:

Indications for Use

510(k) Number (if known): K142043

Device Name: InSync ZR High Translucency Zirconia

Indications for Use: InSync ZR High Translucency Zirconia blanks are intended for use in construction of dental crowns, copings, inlays, and fixed partial dentures up to 3 units. While primarily intended for full contour crowns and bridges, it is also suitable for copings and substructures.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section D: K142043

510(k) Summary

Submitted by: Jensen Industries, Inc.
50 Stillman Road
North Haven, CT. 06473 USA
(203) 239-2090 phone
(203) 285-2990 fax
Contact: Jordan Schreck

Date Prepared: July 18, 2014

Device Name:	InSync ZR High Translucency Zirconia
Common Name:	Dental Ceramic
Classification Name:	Porcelain powder for clinical use (21 CFR 872.6660)
Classification:	Class II
Product Code:	EIH
Predicate Device	NexxZr T; 510(k) number: K130991

Device Description

InSync ZR High Translucency Zirconia is a y-tzp (yttria stabilized tetragonal zirconia polycrystals) material that features very high translucency. It is intended for use in construction of dental crowns, copings, inlays, and fixed partial dentures up to 3 units using CAD/CAM technology. While primarily intended for full contour crowns and bridges, it is also suitable for copings and substructures. InSync ZR High Translucency Zirconia meets requirements for Class 5 (type II) ceramics when tested according to ISO 6872:2008.

Indications for Use

InSync ZR High Translucency Zirconia blanks are intended for use in construction of dental crowns, copings, inlays, and fixed partial dentures up to 3 units. While primarily intended for full contour crowns and bridges, it is also suitable for copings and substructures.

Physical Properties

Non-clinical testing was performed to confirm adherence to the mechanical and chemical properties required of ISO 6872:2008 as a Class 5 (type II) ceramic including flexural strength and chemical solubility.

Biocompatibility

Zircona has a long track record in the medical and dental space because of its strength, chemical stability and high biocompatability. InSync Zr High Translucency Zirconia follows numerous other dental ziconias to market, including the predicate device, that have established a strong product history that has been formally reported upon favorably in various clinical studies.

Updated

Comparison to Predicate Device

Being a Class 5 dental ceramic per ISO 6872:2008, as opposed to a Class 6 for NexxZr T, InSync ZR High Translucency Zirconia carries with it a 3 unit restriction for bridges. This change in intended use is a result of a lower flexural strength measure – a trade off to achieve higher translucency – but is in keeping with the general indications for NexxZr T and other dental zirconias on the market.

Outside of this Class related deviation, all other elements related to handling, design, mechanical properties, chemical composition, biocompatability and indications for use demonstrate InSync ZR High Translucency Zirconia to be substantially equivalent to the predicate device NexxZr T. With both materials meeting their respective non-clinical technical properties measures per ISO 6872:2008, a similar standard of safety and effectivness has been acheived.

Updated